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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,743	11/21/2000	Rajesh Ranganathan	01997/521003	1951

21559 7590 06/16/2004

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/717,743	RANGANATHAN ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24* is/are allowed.

6)☒ Claim(s) *1,3,5 and 22* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2004 has been entered.

DETAILED ACTION

This application filed November 21, 2000, is a continuation in part of application 09/559,622, filed April 27, 2000, which claims benefit to 60/131,149, filed April 27, 1999.

Applicants' amendment filed March 26, 2004, has been received and entered. Claims 2, 4, 6-21 have been canceled. Claims 22-24 have been added. Claims 1, 3, 5, 22-24 are pending.

Election/Restriction

Election was made without traverse in Paper No. 11. Claims 1, 3, 5, 22-24 are pending. Newly added claims 22-24 are drawn to the elected invention. Claims 1, 3, 5 22-24 are currently under examination as they are drawn to a substantially pure nucleic acid sequence encoding a serotonin-gated anion channel.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 3 and 5 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3 and 5 of copending Application No.09/559,622 is withdrawn.

As indicted by Applicants (Applicants' amendment, bottom of page 3), a review of 09/559,622 indicates that claims 1, 3 and 5 have been cancelled. Cancellation of the claims obviates the basis of the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5 rejected under 35 U.S.C. 102(b) as being anticipated by Olde *et al.*, Ramamoorthy *et al.*, Demchyshyn *et al.*, Corey *et al.* or Blakely *et al.* (each present in the IDS) is withdrawn.

Applicants review the teaching of each of the cited references are argue that none of the references anticipate a sequence encoding a serotonin-gated anion channel as required by claim 1. See Applicants' amendment pages 4-5. Applicants' arguments have been fully considered, and found persuasive.

The amendment to the claims has obviated the basis of the rejection. As noted by Applicants, Examiner agrees that neither Olde *et al.*, Ramamoorthy *et al.*, Demchyshyn *et al.*, Corey *et al.* nor Blakely *et al.* teach an serotonin-gated channel with the properties required by the instant claims. Newly added claims 22 and 23 depend on claim 1 therefore encompass these embodiments. Newly added claim 24 encompasses a specific sequence set forth in SEQ ID NO: 3 which is demonstrated in the instant disclosure to have the properties of a serotonin-gated anion channel.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. While the specification and the art provides adequate written description for the isolated nucleic acid sequence set forth as SEQ ID NO: 2 and the encoded amino acid sequence set for as SEQ ID NO: 3, the specification fails to adequately describe other nucleic acid sequences that encode a serotonin-gated anion channel, or even more generally what would be considered or defined as a "MOD-1" serotonin-gated anion channel that differentiates it from another serotonin-gated anion channel sequence which is not MOD-1. Even a sequence that hybridize to the specific disclosed sequences fails to adequately set forth with any specificity the essential elements of the polynucleotide that distinguish it as a serotonin-gated anion channel or a MOD-1. Examiner acknowledges that the protein represented by SEQ ID NO: 3, which is encoded by

the nucleic acid sequence set forth in SEQ ID NO: 2, has the properties of a serotonin-gated anion channel. However, this is only a single species isolated from on species of animal of the potential infinite number of species encompassed by the instant claims. The definition provided by the specification of the invention of MOD-1 taught is described as a serotonin-gated ion channel (page 4; line 8), however this includes other forms of the anion channel including sequences from any animal sources, and a variant or mutant of the 5HT receptor (pages 5-7). Importantly, the disclosed sequence is part of a family of proteins known to be ion channel receptors, and while the specification teaches that "the polypeptide is a subunit that makes up a multi-subunit serotonin-gated anion channel" (page 6, lines 4-6), it fails to point out with any particularity of even in the single species disclosed any critical or distinguishing feature of the polynucleotide sequence that gives it the claimed properties. Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

> In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming

> rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

As applied to the instant circumstances the disclosure of a single sequence fails to describe all the potential serotonin-gated anion channels that exist or could be made, or even set forth what is specifically encompassed by the term "MOD-1". The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case, Applicants have cloned and defined a single sequence from one species of animal and teach the cDNA and the encoded protein providing a biochemical characterization of the protein in the context of a cell, however the specification fails to describe the relevant identifying characteristics that the nucleic acid sequences. The skilled artisan cannot envision all the possible variant nucleic acid sequences which would hybridize and provide the specific property of being an anion channel, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Examiner would not dispute that one could use the disclosed sequence to identify other related sequences and that those sequences could be assayed for the desired properties, however the requirement that a sequence would have to be further characterized supports that written description requirement has not been satisfied.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Similarly, the disclosure of one species termed MOD-1 fails to adequately describe other MOD-1 from other species, or more generally define a serotonin-gated anion channel encompassed by the claims. Therefore, only the recited SEQ ID NOs provided in the instant disclosure meet the written description provision of 35 U.S.C. §112, first paragraph.

Conclusion

Claim 24 is allowed. Claim 23 is objected because it is dependent on a rejected claim, however would be found allowable if rewritten in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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